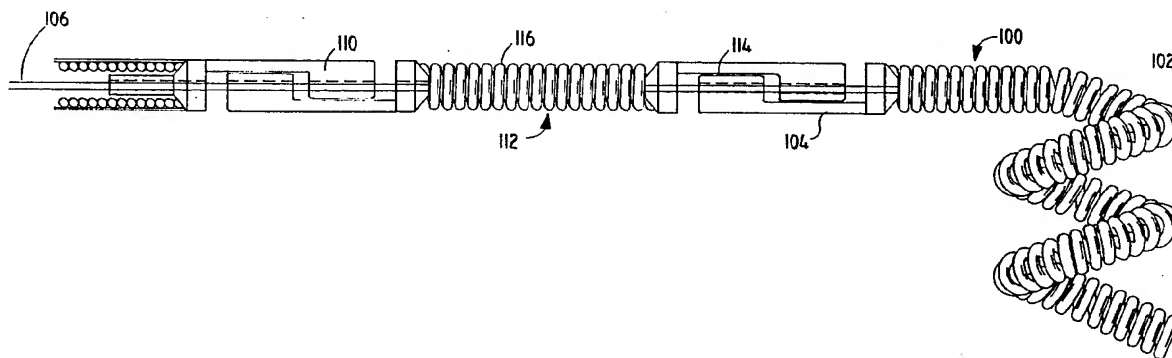




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 29/00	A1	(11) International Publication Number: WO 94/06503 (43) International Publication Date: 31 March 1994 (31.03.94)
(21) International Application Number: PCT/US93/08581 (22) International Filing Date: 13 September 1993 (13.09.93) (30) Priority data: 07/949,094 22 September 1992 (22.09.92) US 08/049,577 19 April 1993 (19.04.93) US (71) Applicant: TARGET THERAPEUTICS, INC. [US/US]; 47201 Lakeview Boulevard, P.O. Box 5120, Fremont, CA 94537-5120 (US). (72) Inventors: PALERMO, Thomas, J. ; 315 So. 13th Street, San Jose, CA 95112 (US). GIA, Son ; 3855 Topock Court, San Jose, CA 95111 (US). (74) Agents: WHEELLOCK, E., Thomas et al.; Morrison & Fo- erster, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).		(81) Designated States: AU, CA, CZ, FI, HU, JP, KR, NO, NZ, SK, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>

(54) Title: DETACHABLE EMBOLIC COIL ASSEMBLY**(57) Abstract**

This invention is a surgical instrument and specifically is a device for delivering embolic coils (102) to a selected site within the vasculature of a human body via use of a catheter. The invention further includes the coils (102). In particular, the device uses embolic coils having interlocking ends, e.g., clasps (114) or hooks (318), on the ends of the coils. The coils may further be secured to each other by a control wire within the catheter. Retraction of the optional control wire (106) into the catheter body uncouples the distal coil.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LJ	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

5

DETACHABLE EMBOLIC COIL ASSEMBLYRELATED APPLICATIONS

This is a continuation-in-part of U.S. patent application Ser. No. 07/949,094, filed September 22, 1992, (Docket No. 29025-20046.00) entitled "Detachable Embolic Coil Assembly Using Interlocking Clasps," and Ser. No. 08/049,577, filed April 19, 1993, (Docket No. 29025-20076.00) entitled "Detachable Embolic Coil Assembly Using Interlocking Hooks and Slots," the entirety of which are incorporated by reference.

FIELD OF THE INVENTION

This invention is a surgical instrument and specifically is a device for delivering embolic coils to a selected site within the vasculature or other lumen of a human body via use of a catheter. The invention further includes the coils. In particular, the device (typically a "pusher assembly" in conjunction with a catheter) uses embolic coils having interlocking ends, e.g., clasps or hooks, on at least one end of the coils. The coils may further be secured to each other by a control wire within the catheter. The coils are pushed out the end of the catheter for placement and retraction of the optional control wire into the catheter body uncouples the distal coil. If no control wire is used, the coil is self-disengaging.

BACKGROUND OF THE INVENTION

The endovascular treatment of a variety of vascular maladies throughout the body is an increasingly

more important form of therapy. Catheters have been used to place various treatment materials, devices, and drugs within arteries and veins in the human body. Examples of these devices and their use in such treatments are shown in

5 U.S. Patent Application Nos. 07/806,898 ("Detachable Pusher-Vasocclusive Coil Assembly with Threaded Coupling") and 07/806,912 ("Detachable Pusher-Vasocclusive Coil Assembly with Interlocking Ball and Keyway Coupling"). These show methods and devices for delivery of coils or

10 wires within the human body to sites such as aneurysms, to occlude those sites. Coils such as are discussed in U.S. Patent No. 4,994,069, may be of a regular or helical configuration or assume a random convoluted configuration at the selected site. The coils normally are made of a

15 radiopaque, biocompatible metal such as platinum, gold, tungsten, or alloys of these and other metals.

In treating aneurysms it is common to place a number of coils within the aneurysm. The coils occlude the site by posing a physical barrier to blood flow and by

20 promoting thrombus formation at the site.

Coils have typically been placed at the desired site within the vasculature using a catheter and a pusher. The site is first accessed by the distal end of a catheter. In treating peripheral or neural conditions requiring

25 occlusion, the sites are accessed with flexible, small diameter catheters such as those shown in U.S. Patent Nos. 4,739,768 and 4,813,934. The catheter may be guided to the site through the use of guidewires (see U.S. Patent No. 4,884,579) or by flow-directed means such as balloons

30 placed at the distal end of the catheter. Use of guidewires involves the placement of relatively long, torqueable proximal wire sections within the catheter, which proximal sections are attached to more flexible distal end wire section designed to be advanced across

35 sharp bends at vessel junctions. The guidewire is visible

using x-ray and allows a catheter to be manipulated through extremely tortuous vessels, even when such vessels are surrounded by soft tissue such as the brain.

5 Once the selected site has been reached, the catheter lumen is cleared by removing the guidewire (if a guidewire has been used), and the coil is placed into the proximal open end of the catheter and advanced through the catheter with a pusher. Pushers are wires having a distal end that is adapted to engage and push the coil through the
10 catheter lumen as the pusher is advanced through the catheter. When the coil reaches the distal end of the catheter, it is discharged from the catheter by the pusher into the vascular site. This technique of discharging the coil from the distal end of the catheter has a number of
15 undesirable limitations. First, because of the plunging action of the pusher and the coil, the positioning of the coil at the site cannot be controlled to a fine degree of accuracy. Second, once the coil has left the catheter, it is difficult to reposition or retrieve the coil if such is
20 desired. Nevertheless, the technique has the benefit of delivering multiple coils at low cost with a short delivery time.

Several techniques have been developed to enable more accurate placement of coils within a vessel. In one
25 technique (U.S. Patent No. 5,122,136, issued June 16, 1992) the coil is bonded via a metal-to-metal joint to the distal end of the pusher. The pusher and coil are made of dissimilar metals. The coil-carrying pusher is advanced through the catheter to the site and a low electrical
30 current is passed through the pusher-coil assembly. The current causes the joint between the pusher and the coil to be severed via electrolysis. The pusher may then be retracted leaving the detached coil at an exact position within the vessel. In addition to enabling more accurate
35 coil placement, the electric current may facilitate

thrombus formation at the coil site. The only perceived disadvantage of this method is that the electrolytic release of the coil requires a period of time so that rapid detachment of the coil from the pusher does not occur.

5 Another technique for detaching an embolic coil is shown in U.S. Patent Application 07/806,912. In that document, a coil having an enlarged portion is mated with a pusher having a keyway adapted to receive the enlarged portion of the coil in an interlocking relationship is
10 covered by a coaxial member about the pusher and the coil. The coaxial member is movable by sliding the member axially. As the coaxial member is moved away from the junction where the coil's member engages the member of the keyway of the pusher, the coil disengages and the pusher is
15 removed.

 Another device for placement of coils is shown in U.S. Patent Application 07/806,898. This device includes a coil having a helical portion at one end and a pusher which is threaded to the inside of the helical coil by the
20 use of a threaded section on the outside of the pusher. The device operates to release the coil by engaging the proximal end of the coil with a sleeve while the pusher is unthreaded. Once the pusher is free, the sleeve may be used to push the coil out into the treatment area.

25 Another method of placing an embolic coil is shown in U.S. Patent No. 5,108,407. This patent shows the use of a device in which embolic coils are separated from the distal end of a catheter by the use of heat-releasable adhesive bonds. The coil adheres to the therapeutic device
30 via a mounting connection using a heat sensitive adhesive. Laser energy is transferred through a fiber optic cable, which cable terminates at the connector. The connector becomes warm and releases the adhesive bond between the connector and the coil.

35

None of these disclosed devices suggest coils having interlocking ends which allow an embolic coil to be positioned within a vessel and then released upon ejection of the coil from the catheter distal end or, optionally, upon retraction of a control wire positioned within that interlocking end.

SUMMARY OF THE INVENTION

This invention is a device for placing detachable coils within the vasculature of the human body so to occlude that site with the coils. The device includes a coil that carries an interlocking connector or end such as a slot, hook, or clasp at at least one end of the coil, preferably at its proximal end. The device includes a pusher (positioned within the catheter) which has a cooperating connector at its distal end which interlocks with the connector or end situated on the coil. The coils may have interlocking clasps at each end thereby allowing a number of coils to be strung together and yet individually released. The coil may alternatively carry a receiving slot on at least one end of the coil adapted to cooperatively receive a hook which is shaped to engage the receiving slot. The coil having such a receiving slot may also have such a hook at the end of the coil distant from the receiving slot. An optional control wire passing through the catheter, the pusher assembly, the pusher clasp, and the coil ends releases the coil as the control wire is retracted through axial passageways or openings provided in the two clasps.

Another portion of the invention is a method for occluding a selected vascular site comprising the steps of: (a) accessing the site with a distal end of a catheter; (b) advancing the assembly described above through the catheter with the coil interlocked with the pusher to a position out the end of the distal end of the catheter; (c) disengaging

the coil optionally by withdrawing the control wire from the coil; and (d) withdrawing the catheter and pusher from the vessel.

5 BRIEF DESCRIPTION OF THE DRAWINGS

 Figures 1A and 1B show, respectively, a partial sectional view of a pusher assembly and an engaged coil assembly having an interlocking clasp at only one end and a front three-quarters view of one variation of the
10 interlocking clamp.

 Figure 2 shows a series of coil assemblies having either one or two interlocking clasps at their ends.

 Figure 3 shows deployment of the interlocking coil within a catheter.

15 Figures 4 and 5 show the operation of the assembly as it places a coil within a target site.

 Figures 6A and 6B show, respectively, a partial sectional view of a pusher assembly and an engaged coil assembly having a variation of an interlocking clasp and a
20 front three-quarter view of that variation of the interlocking clasp.

 Figures 7A, 7B, and 7C show a method of attaching coils having the interlocking clasp shown in Figures 6A and 6B to a pusher body within the catheter lumen.

25 Figure 8 shows a variation of the invention in which both the coils and the pusher body have simple loops as interlocking clasps.

 Figure 9A shows a side view of a clasp, joinable to a coil or pusher, similar in shape to the Figure 1A to
30 5 clasp but, in design without, without the control wire.

 Figure 9B shows a front three-quarter view of the Figure 9A clasp.

 Figure 10A shows a side view of a clasp similar to the clasp shown in Figures 9A and 9B but with a ramped
35 end.

Figure 10B shows a front three-quarter view of the Figure 10A clasp.

Figure 11 shows the Figure 9A clasp mounted on a pusher and on a coil as would be seen in a catheter.

5 Figure 12 shows in partial cross-sectional view, a guidewire pusher assembly having a W-shaped hook at the distal end for engaging coils having a cooperatively shaped slot.

10 Figure 13 shows the distal tip of a variation of the guidewire pusher shown in Figure 12 but having a simply V-shaped hook positioned at the distal end.

Figure 14 shows the distal tip of a variation of the guidewire pusher shown in Figure 12 but having a solid hook positioned at the distal end.

15 Figure 15 shows an embolic coil having the desired engaging slot at one end.

Figure 16 shows a coil similar in construction to that found in Figure 15, but also having a hook at its other end.

20 Figure 17 shows an embolic coil similar to that in Figure 15 and a pusher similar to Figure 14 using a control wire to allow disengagement of the coil.

Figure 18 depicts the manner in which the invention operates.

25

DESCRIPTION OF THE INVENTION

The coil assembly (100) is shown in Figure 1. The coil (102) is shown as helical in form, although it may be any other suitable form. The coil should be of a size
30 sufficiently small that it may be advanced through a catheter that is appropriately sized for accessing the targeted vascular site. For instance, when accessing a brain aneurysm in a small vessel, an appropriately sized catheter is quite small and very flexible. The coil in

35

such a situation must be small enough to fit through the catheter and out its distal end at the treatment site.

The coil is desirably made up of a radiopaque, physiologically compatible material. For instance, the material may be platinum, gold, tungsten, or alloys of these. Certain polymers are also suitable as coil material either alone or in conjunction with metallic markers providing radiopacity. These materials are chosen so that the procedure of locating coils within the vessel may be viewed using radiography. However, it is also contemplated that these coils may be made of various other biologically inert polymers or of carbon fiber.

The size of the coil and its constituent winding will depend upon the use to which the coil will be placed. For occluding peripheral or neural sites, the coils will typically be made of 0.05 to 0.15 mm diameter wire (platinum or platinum/tungsten alloy) that may be wound to have an inner diameter of 0.15 to 1.5 mm with a minimum pitch -- that is to say that the pitch is equal to the diameter of the wire used in the coil. The outer diameter is then typically between 0.25 mm to 1.8 mm. The length of the coil will normally be in the range of 0.5 to 60 cm, preferably 0.5 to 40 cm.

If desired, the coil may be formed in such a way that the coil is essentially linear as it passes through the catheter and yet assumes a randomly oriented relaxed condition after it is released from the distal end of the catheter. A discussion of this variation may be found in U.S. Patent No. 4,994,069.

Fixedly attached to coil (102), as is shown in Figure 1A, is interlocking clasp (104). Interlocking clasp (104) as is depicted in the front three-quarter view in Figure 1B, has an interior passageway allowing the control wire (106) to pass completely therethrough. As is shown in Figure 1A, the male portion of the next adjacent

interlocking clasp (110) fits into the area (108) left within clasp (104) so to allow the interlocking to take place. Said another way, the distal portion of interlocking clasp (104) is generally cylindrical in shape but has a surface (107), which may be cut or milled away, allowing the portion to mesh within the middle area (108) of an adjacent clasp. The proximal section is adapted for attaching to a coil or to a pusher assembly. The attachment may be by welding, soldering, gluing, or the like. With a control wire (106) passing through the axis of both interlocking clasps (104) and (110), the two are locked together. As is shown in Figure 1A, the control wire may extend through the length of coil (102).

Figure 2 shows an intermediate coil assembly (110) comprising coil (102) and interlocking clasp (104) (joined with coil assembly (112)) which has interlocking clasp (114) fixedly attached at both ends of the intervening coil (116). As was the situation in Figure 1A, the proximal interlocking clasp (114) is joined by control wire (106) with interlocking clasp (110). In this way, a significant number of coils (112) may be loaded onto a control wire (106) and delivered to the treatment site without removal of the control wire from the catheter.

Figure 3 shows the relationship of coil assembly (100) and the pusher assembly (118) with its distal interlocking clasp (110) as it fits within catheter sheath (120). Also shown is movable inner core member (122) and the sheath (124) which fits within catheter sheath (120) and supports interlocking clasp (110). Shown in Figure 3 is the stiffener spring (126) which provides form and support for the distal end of the pusher assembly (118) and in particular rigidly adheres to interlocking clasp (110). Inner core member (122) allows the control wire (106) to be moved axially along the interior of the catheter sheath (120) and the pusher assembly (118). Movement of the inner

core member (122) in a proximal direction permits uncoupling of the coil as will be discussed in more detail below.

5 The length of pusher assembly (118) will be such as to be capable of being advanced entirely through the catheter to place coil (102) at the target site but yet with a sufficient portion of the proximal end of the pusher assembly (118) protruding from the proximal end of the catheter to enable the control wire (106) to be
10 manipulated. For use in peripheral or neural surgeries, the pusher will normally about 100-200 cm in length, more normally 130-180 cm in length. The diameter of the pusher assembly (118) is usually in the range of 0.25 to about 0.90 mm.

15 As indicated previously, conventional catheter insertion and navigational techniques involving guidewires or flow-directed devices may be used to access the site with a catheter. Once the distal end of the catheter is positioned at the site, often by locating its distal end
20 through the use of radiopaque marker material and radiography, the catheter is cleared. For instance, if a guidewire has been used to position the catheter, it is withdrawn from the catheter and then the pusher assembly (118) having coil assembly (100) at the distal end is
25 advanced through the catheter. The pusher assembly (118) is advanced past the distal end of the catheter so that the coil is free of the catheter and with the coil positioned precisely at the desired treatment site.

30 As is shown in Figures 4 and 5, control wire (106) is withdrawn from the junction between coil interlocking clasp (104) and the other interlocking clasp (110). Coil assembly (100) is then free. The entire catheter may then be removed or the pusher assembly (118) may be withdrawn from the catheter lumen to provide for
35 installation of other coils. If additional coils are to be

placed at the target site, the procedure is repeated. After the desired number of coils have been placed at the site, the catheter is withdrawn from the vessel.

Figure 6A shows a variation in which coil assembly (128) is interlocked with pusher assembly (130) by control wire (106). The depicted coil assembly (128) and pusher assembly (130) are different in that they incorporate the interlocking clasp (132) design shown more clearly in Figure 6B. The interlocking clasp (132), as with the clasp depicted in Figure 1B, utilizes an open area (134) within the clasp (132) to accept the mating ramp latch (136) from another similar clasp. The ramp latch (136) typically has a slot (138) and a passageway (140) to permit passage of the control wire through the clasp (132) from end to end without obstruction.

The ramp latch (136) allows easy assembly of a string of coils within the catheter for subsequent placement using the device.

Such an assembly process is shown in Figures 7A, 7B, and 7C.

Figure 7A shows a pusher assembly (130) approaching a coil assembly (128) which has been previously placed within a catheter sheath (120). The distal interlocking clasp (132) on the pusher assembly (130) is positioned to interlock with the proximal interlocking clasp (134) on the coil assembly (128).

Figure 7B shows the two interlocking clasps (132 and 134) as they approach their respective ramps contacting and causing the two clasps to displace axially within the catheter sheath.

Figure 7C shows the location of the coil assembly (128) and the pusher assembly (132) after the respective clasps are interlocked and the control wire (106) has been placed through the passageways within the clasps.

Figure 8 shows an elegantly simple variation of the invention in which the pusher (138) is a tubing member having a control wire (106) within its core. The clasp portion (140) is a simple loop comprising, e.g., wire or small rod. The corresponding interlocking loop (142) on the coil (144) forms the junction with the clasp on the pusher.

The variation of the invention shown in Figures 6A, 6B, 7A, 7B, 7C, and 8 may be placed within the vasculature in the same manner as shown for the variation shown in Figs. 4 and 5.*****

Figure 9A shows a side view of a clasp (160) similar in design to the clasp discussed in conjunction with Figures 1A, 1B, 2, 3, 4, and 5. In contrast to the clasp found on those vasoocclusive devices, the Figure 9A clasp (160) contains no lumen therethrough for a control wire. As was the case with the clasp above, the clasp is generally cylindrical in shape but has a surface (162) which may be cut or milled away to allow the to mesh with a receiver area (164) in the next adjacent clasp as is shown in Figure 11. The other end of the clasp is adapted to allow joining with the end of a coil or pusher. Although that other end is shown with a reduced diameter (166), to allow insertion of the end (166) into the coil or pusher, other end shapes are certainly appropriate, e.g., helical to accept the coil, square, bulbed, etc., the reduced diameter cylinder is very desirable. The vertical or mating surface (168) pulls the next device in the chain along when it contacts the similar surface in that next device. The end surface (170) pushes against the next device when in a chain.

Figure 9B shows a front, elevated, three-quarter view of the clasp found in Figure 9A. Figure 9B shows the end surface (170), the receiver area (164), and the reduced diameter shaft (166) for mating with the coil or pusher.

Figure 10A shows a clasp (172) much like that shown in Figure 9A except that the end surface is a ramp (174) to permit assembly ease in placing the coils in the catheter or introducer.

5 Figure 10B shows a front, elevated, three-quarter view of the clasp found in Figure 10A. Figure 10B shows the end ramp (174), the receiver area (164), and the reduced diameter shaft (166) for mating with the coil or pusher.

10 Figure 11 shows how the clasps found in Figures 9A and 9B mesh when installed on a pusher (178) or a coil (180). It is within the scope of this variation of the invention that the clasp be mounted on the ends of pushers, coils (one or both ends), and that multiple coils or other
15 vasoocclusive devices be joined in multiple end-to-end trains for introduction into the vasculature.

 An additional variation of the pusher assembly (200) is shown in Figure 12. The configuration of the body of the pusher assembly (200) is not particularly critical, and many variations known in the art would likely be
20 suitable. The variation shown here entails, at the distal end, a stainless steel core (202) having a small diameter section (204) covered by a desired polymeric material (206) such as tetrafluoroethylene, or other suitable fluorinated
25 hydrocarbon polymers; hydrophilic polymers such as polyvinylpyrrolidone, polyethyleneoxide, or polyhydroxyethylmethacrylate, or copolymers, or mixtures, or blends thereof; or various silicone-based polymeric materials; or polyolefins such as polyethylene,
30 polypropylene, or their copolymers, mixtures, or blends; or appropriate polyurethane polymers. This coating provides a slippery surface allowing ease of insertion and traverse through the catheter body.

 It is desirable to include a radiopaque marker
35 (208). Such markers are common in this art and may be made

of known radiopaque materials such as platinum, palladium, or other such materials. Commonly, the radiopaque marker (208) is a coil which is brazed or soldered to the guidewire and may be coated with the polymeric materials (206). This marker allows the tending physician to monitor the progress of the guidewire tip via fluoroscopy and, obviously, allow proper placement of the coil which is attached to the end of the pusher guidewire (200).

More distal of the radiopaque marker (208) may be found a flexible coil (210). This coil covers a tapered section of the core wire (202). Tapering the inner wire and enclosing it in a wire coil increases the column strength of the tapered wire section without significant loss of flexibility and increases the radial capacity of the guidewire to allow fine manipulation of the guidewire through various tortuous portions of the vasculature. The tip of the core wire (202) and the distal portion of the wire coil (210) are typically joined by use of a solder joint (212). To this point, the guidewire is of a typical guidewire respected in this art. See, for instance, those guidewires shown in U.S. Patent Nos. 3,789,841; 4,545,390; and 4,619,274.

Unique to this variation of the invention is the hook (214) placed at the most distal end of the guidewire assembly (200) which transforms it into a pusher.

Engaging hook (214) has two legs (216) which are based in solder joint (212). The outer hook portion (218) is configured so that it slides into the conforming slot in the coils as discussed below. The diameter (220) of the hook (214) is typically no larger than the inside diameter of the catheter assembly into which it is placed. Obviously, if the diameter is larger, it will bind in the catheter and be of little use. The most distal portion of the hook (218) is configured in such a way that the "W" portion is in a plane which is generally perpendicular to

the longitudinal axis of the guidewire pusher assembly (200). The engaging hook (214) need be made only of a material which is adequate under the circumstances of use. For instance, the hook may be of a stainless steel wire which may be soldered onto the end of the guidewire assembly (200) and bent into desirable shape. In this way, the hook may be used to push the attached coil through the catheter without bending. The length of guidewire pusher assembly (200) should be such as to be capable of being advanced entirely through a catheter to place a coil such as discussed below at the target site, but yet retain a sufficient portion of the proximal end of the guidewire pusher assembly (200) protruding from the proximal end of the catheter to enable the pusher to be manipulated. For use in peripheral and neural surgeries, the pusher will normally be about 100-200 cm in length, more normally 130-180 cm in length. The diameter of the guidewire pusher assembly (100) is usually in the range of 0.25 to about 0.90 mm.

Figure 13 shows a variation of the distal tip of guidewire pusher assembly (200) having a slightly different configuration than that shown in Figure 12. In this instance, the hook is a simple "V"- or "U"-shaped hook which also will engage with the slotted coils described below. The materials of construction and other such variables are similar to those for the hook of Figure 12. Figure 14 shows an additional variation of the pusher assembly (200) having a hooked distal tip. This hook (223) is of a bent ribbon rather than the wire configuration shown in Figures 12 and 13. The materials of construction and method of attachment are similar to those used in the Figure 12 and 13 variations. The ribbon is bent in such a way as to allow insertion of the hook's bent lip into the slot found in the coils discussed below.

The coil typical of that which might be used with this invention, is shown in Figure 15. The coil (300) is shown as helical in form, although it may be any other suitable form. The coil shown is one having a primary and a secondary diameter. The primary diameter (302) is sufficiently small that the coil (300), when straightened, would fit inside the lumen of the catheter assembly. The coil assembly shown assumes a second diameter (304) when ejected from the tip of the catheter using the pusher guidewire (200) shown in Figure 12.

Coil (300) may be made up of the same or similar radiopaque, physiologically compatible materials discussed in relation to coil (100) applicable to Figures 1-5 above. The size, length, diameter (inner and outer), pitch, and configuration all may be as discussed above.

Whatever the configuration may be, the coil typically has caps at each end. Specifically, the distal end of the coil (300) will have a distal cap to (306) which may be solder or epoxy or other filling adhesive or fused from the coil metal, preferably forming a rounded form to prevent the coil from hanging up within the catheter or an inappropriate place within the patient's vasculature. The unique aspect of this invention is found at the proximal end of the coil (308). The proximal end typically will be soldered or glued, much in the way that the distal end has been, but is configured in such a way that a slot (310) is opened during the soldering or gluing process and will accept the hook, variously (214) in Figure 12 or (222) in Figure 13 or (223) in Figure 14 into the slot. Obviously, the receiving slot (310) may be generally substantially perpendicular to the local axis of the coil.

Figure 16 depicts a variation of the coil shown in Figure 15. This variation, however, includes, at the distal end of the coil (316), a hook (318) of configuration similar to that found in discussing the guidewire pusher

assemblies in Figures 12 and 13. This configuration allows the introduction of discrete segments of coils into the catheter and separate placement of them should such a situation be desirable. In such an instance, the hook
5 (318) would be introduced into the receiver slot (310) in the similar coil next in line. The most proximal of the coils would, in turn, be engaged with a hook on a pusher assembly such as (200) shown in Figure 12.

Figure 17 shows a variation of the invention
10 shown in Figures 12-16 in which a control wire (240) is placed generally through an axial passageway between the distal (or proximal) end (242) of a coil or pusher having a hook (244) and the corresponding end (246) of a coil (243) having a slot (248) cooperating with the hook (244).
15 As with the variation shown in Figures 1-8, the control wire (240) may be withdrawn when the coil (243) is situated at the selected vascular site to disengage the coil (243). Use of the control wire permits more precise placement of coil (243) and its gentle disengagement.

20 Figure 18 is a side view depicting how the hook (122), as depicted here, is placed in slot (310) of the coil assembly (300). The tip of a typical catheter (400) is shown in the Figure. Again, the overall diameter of the various assemblies as put together for introduction into or
25 out of catheter must be of a diameter smaller than the diameter lumen in catheter (400). Obviously, too large a coil/pusher combination will not be particularly valuable in a situation where such is needed.

As indicated previously, conventional catheter
30 insertion and navigational techniques involving guidewires or even flow-directed devices may be used to access a chosen vascular site with a catheter. Once the distal end of the catheter is positioned at that chosen site, often by locating its distal end through the use of a radiopaque
35 marker material and radiography, the catheter is cleared.

For instance, if a guidewire has been used to position a catheter, it is withdrawn from the catheter and then the guidewire pusher assembly such as (200) shown in Figure 12 having coil assembly such as (300) in Figure 15 is assembled and introduced into the proximal end of the catheter. The guidewire pusher assembly is then advanced so that its distal end is free of the distal end of the catheter and the coil positioned precisely at the desired site. The pusher assembly (200) may require a twisting movement to free the distal hook from the receiving slot in the coil.

Modifications of the device described above and methods of using it in keeping with this invention that are apparent to those having skill in this mechanical and surgical instrument design art and related fields are intended to be within the scope of the claims which follow.

I CLAIM AS MY INVENTION:

1. A detachable coil assembly for use in occluding a selected site within a vessel comprising a coil with opposing ends on a coil axis and having, on at least one end, an interlocking, shaped clasp having an axis generally colinear with the coil axis, said interlocking clasp configured to interlock with a similar clasp.
2. The coil assembly of claim 1 additionally having a axial passageway generally colinear with said coil and where said coil assembly is coupled to said similar clasp by passing a control wire through the axial passageway and where the coil assembly may be uncoupled from said similar clasp by axially withdrawing the control wire from the axial passageway in said clasps.
3. The assembly of claim 1 where the coil is a helical coil.
4. The assembly of claim 3 where the coil has a random or straight configuration.
5. The assembly of claim 1 where the coil assembly has interlocking clasps at each of the coil ends.
6. The assembly of claim 1 in which the interlocking clasp comprises a distal portion of a generally cylindrical shape, a middle portion adapted to accept said cylindrical distal portion from a similar interlocking clasp, and a proximal section adapted for attaching to the coil.
7. The assembly of claim 6 in which the interlocking clasp comprises a generally cylindrical distal

portion having a ramp adapted to engage a ramp on a similar interlocking clasp, a middle portion adapted to accept a cylindrical portion with a ramp or a similar interlocking clasp, and a proximal portion adapted for attaching to the
5 coil.

8. The assembly of claim 1 additionally comprising a control wire therethrough.

10 9. The assembly of claim 8 additionally comprising one or more coil assemblies interlocked by the control wire.

15

20

25

30

35

10. A combination pusher assembly-coil assembly for use in occluding a selected site within a vessel comprising:

5 (a) a coil with opposing ends on a coil axis and having, on at least one end, an interlocking, shaped clasp having an axis generally colinear with the coil axis, said interlocking clasp configured to interlock with a similar clasp; and

10 (b) a pusher assembly comprising a tubular pusher sheath having a proximal end and a distal end and adapted to fit within a catheter sheath and an interlocking clasp located at the distal end of the pusher sheath and said clasp connected to the distal end of the pusher assembly.

15 11. The combination pusher assembly-coil assembly of claim 10 where the coil additionally has an axial passageway generally colinear with said coil axis and where said coil is coupled to said similar clasp by passing a control wire through the axial passageway and where the
20 coil may be uncoupled from said similar clasp by axially withdrawing the control wire from the axial passageway in said clasps, and the pusher assembly has a continuous passageway therethrough for passage of a control wire from the distal end of the pusher sheath to the proximal end of
25 the pusher sheath, and further containing a control wire suitable for passage through the pusher passageway and the coil axial passageway.

30 12. The assembly of claim 10 where the coil is a helical coil.

13. The assembly of claim 12 where the coil has a straight or random configuration.

14. The assembly of claim 10 additionally comprising a catheter sheath disposed about the pusher sheath.

5 15. The assembly of claim 10 additionally comprising more than one coil.

10 16. The assembly of claim 10 in which the interlocking clasps comprise a distal portion of a generally cylindrical shape, but having a middle portion adapted to accept said cylindrical distal portion from a similar clasp to allow interlocking with said similar clasp, and a proximal section adapted for attaching to the coil.

15

17. The assembly of claim 10 in which the interlocking clasps comprise a generally cylindrical distal portion having a ramp adapted to engage a ramp of a similar interlocking clasp, a middle portion adapted to accept a
20 cylindrical portion with a ramp or a similar interlocking clasp, and a proximal portion adapted for attaching to the coil.

25

30

35

18. A detachable coil assembly for use in occluding a selected vascular site comprising a coil with an axis, a distal end, and a proximal end; and having, on
5 at least one of the proximal and distal ends, an open receiving slot generally perpendicular to the coil axis, where the open receiving slot will accept a hook adapted to enter the receiving slot and adapted also to exit the coil slot.
- 10 19. The assembly of claim 18 where the coil is a helical coil.
- 15 20. The assembly of claim 19 where the coil has a random configuration.
21. The assembly of claim 19 where the coil has a straight configuration.
- 20 22. The assembly of claim 18 where the distal coil end comprises a closed hook adapted to enter a receiving slot in a detachable coil assembly.
- 25 23. The assembly of claim 18 where the distal coil end comprises a bent ribbon having a lip adapted to enter a receiving slot in a detachable coil assembly.
- 30 24. The assembly of claim 18 where the coil axis length is 0.5 to 100 cm.
25. The assembly of claim 18 where the coil outer diameter is between 0.25 mm and 1.8 mm.

26. The assembly of claim 18 additionally comprising an axial passageway extending from distal to proximal end.

5

10

15

20

25

30

35

27. A combination pusher assembly-coil assembly for use in occluding a selected vascular site comprising:

5 (a) a coil with an axis, a distal end, and a proximal end; and having, on at least one of the proximal and distal ends, an open receiving slot generally perpendicular to the coil axis, where the open receiving slot will accept a closed hook adapted to enter the receiving slot and adapted also to exit the coil slot; and

10 (b) a pusher assembly comprising a core wire having proximal and distal ends and adapted to fit within a catheter sheath and having a closed hook located at its distal end, said hook adapted to enter the open receiving slot in the distal end of said coil.

15 28. The assembly of claim 27 where the coil is a helical coil.

20 29. The assembly of claim 28 where the coil has a random configuration.

30. The assembly of claim 28 where the coil has a straight configuration.

25 31. The assembly of claim 27 additionally comprising a catheter sheath disposed about the pusher assembly and coil.

30 32. The assembly of claim 27 additionally comprising more than one coil.

33. The assembly of claim 27 where the hook is a closed wire hook adapted to enter said receiving slot.

34. The assembly of claim 27 where the hook is a bent ribbon having a lip adapted to enter said receiving slot.

5

10

15

20

25

30

35

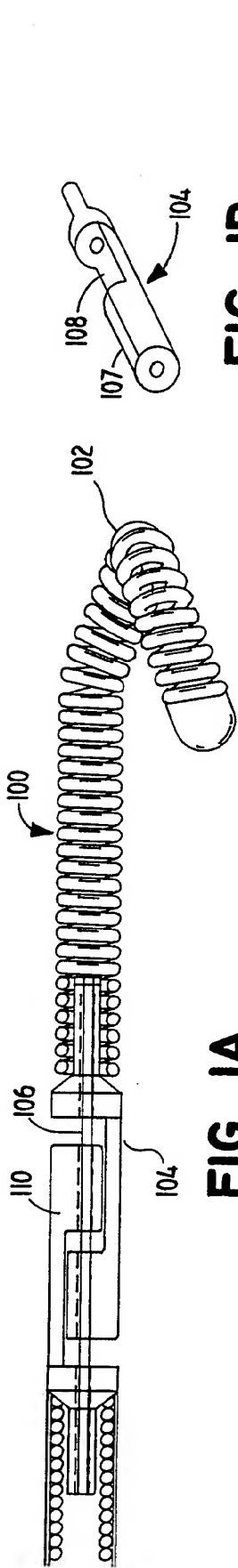


FIG. 1B

FIG. 1A

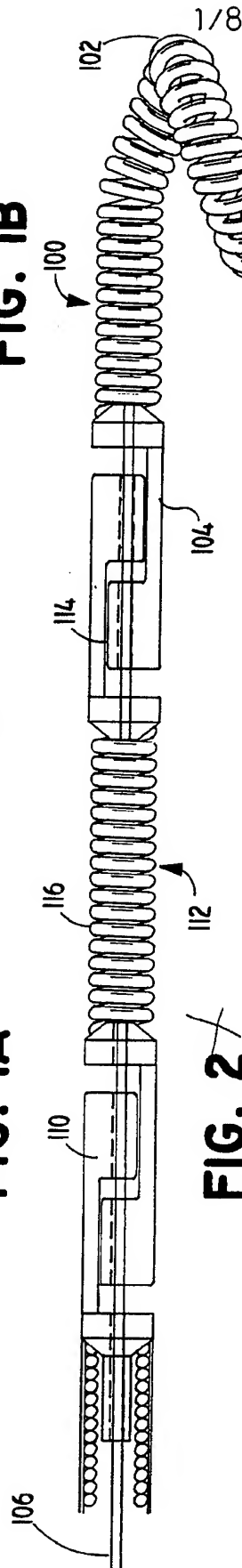


FIG. 2

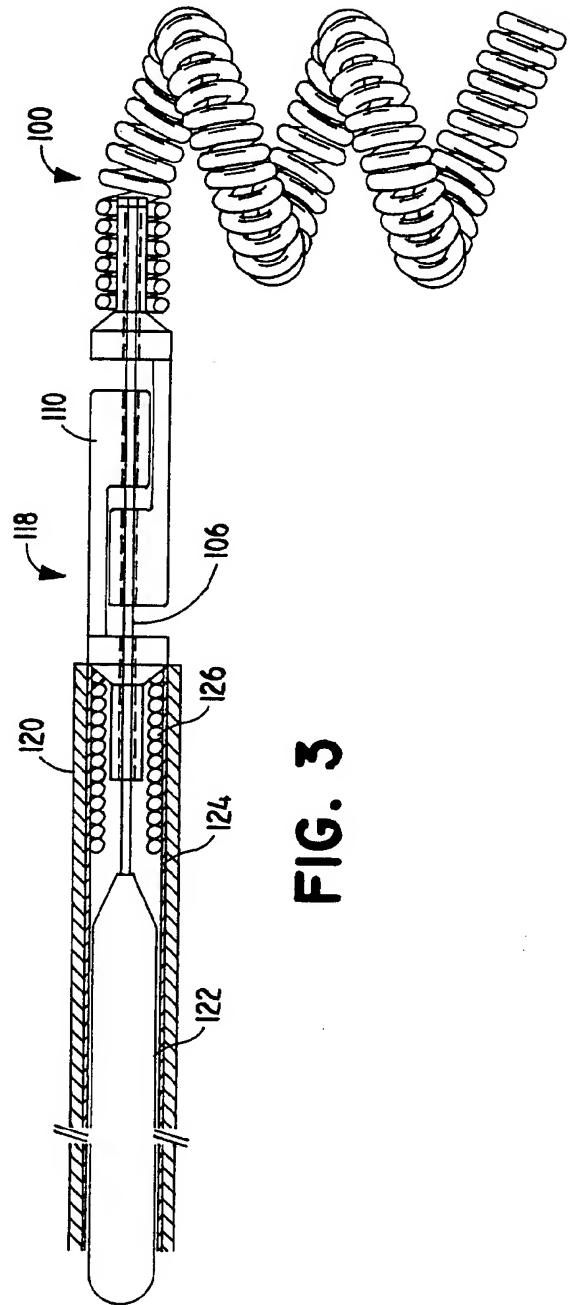
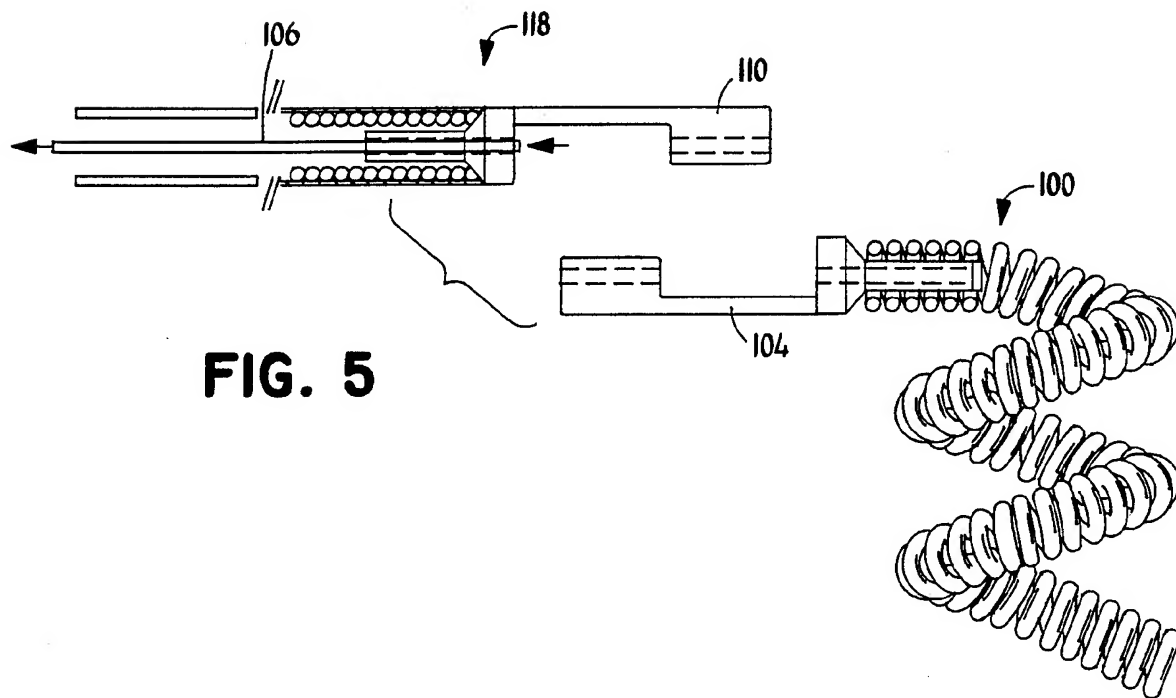
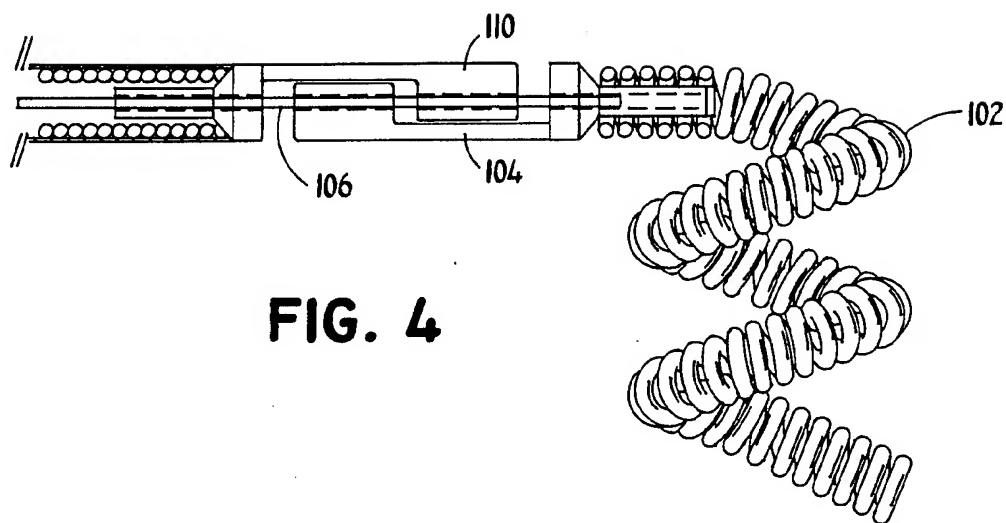


FIG. 3

2 / 8



SUBSTITUTE SHEET

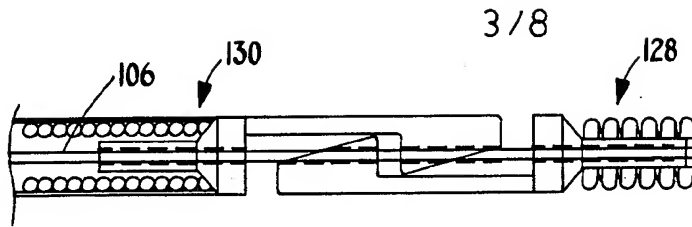


FIG. 6A

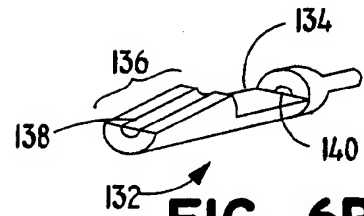


FIG. 6B

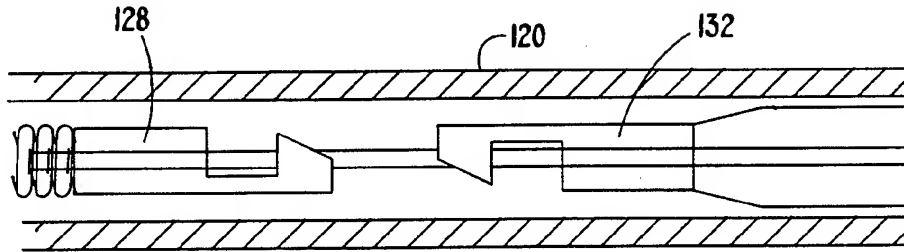


FIG. 7A

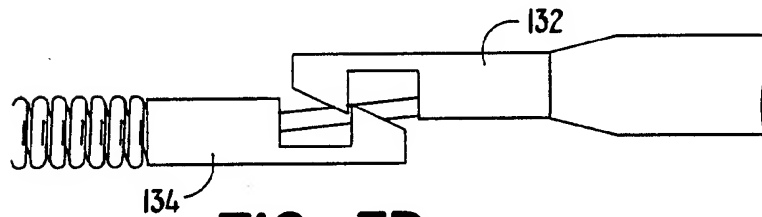


FIG. 7B

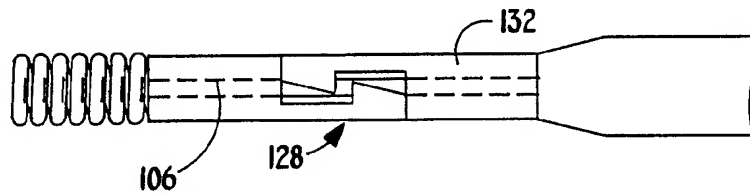


FIG. 7C

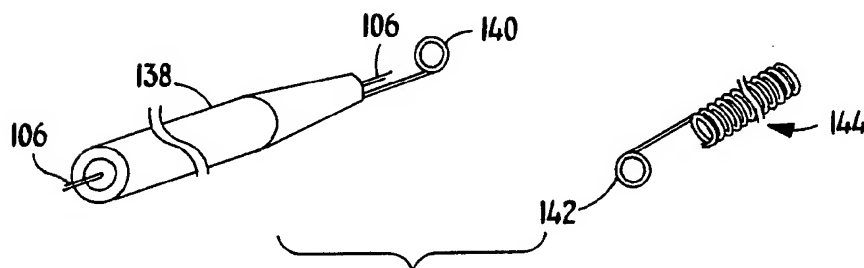
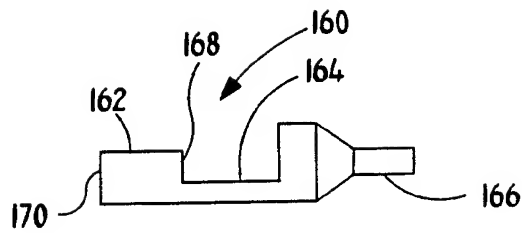
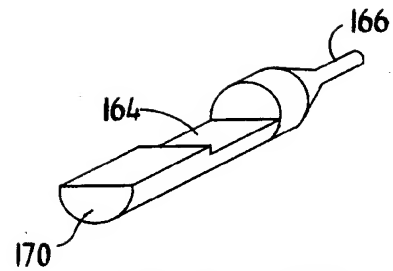
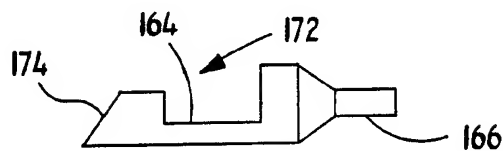
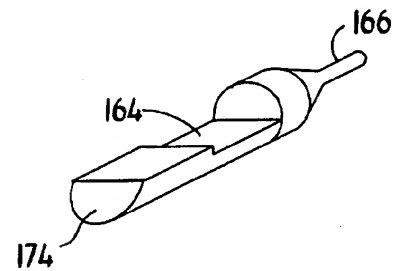
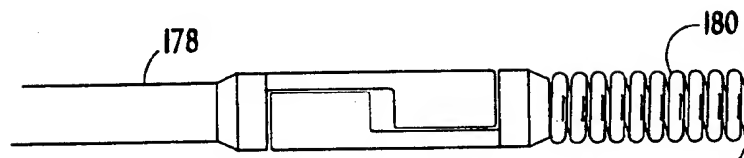


FIG. 8

SUBSTITUTE SHEET

4/8

**FIG. 9A****FIG. 9B****FIG. 10A****FIG. 10B****FIG. II**

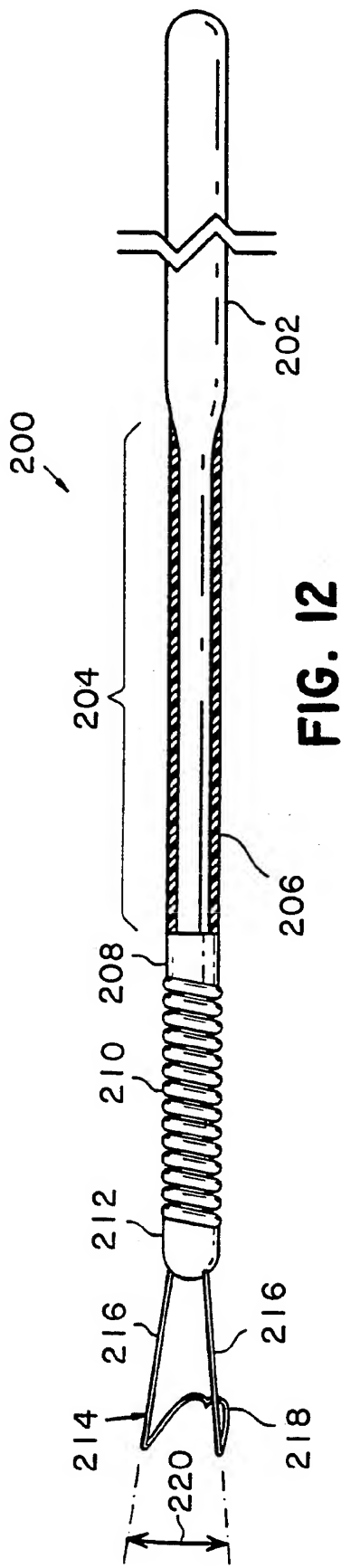


FIG. 12

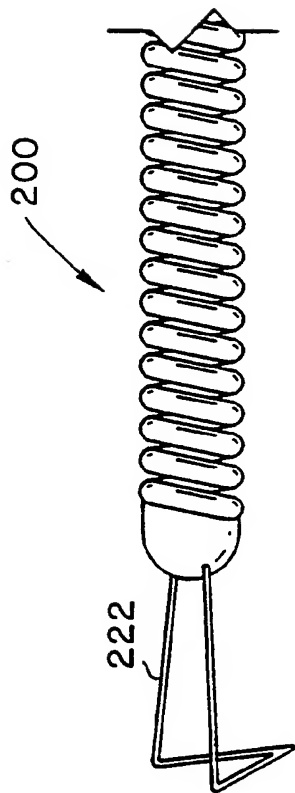


FIG. 13

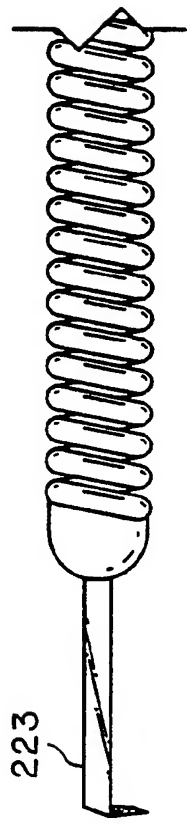
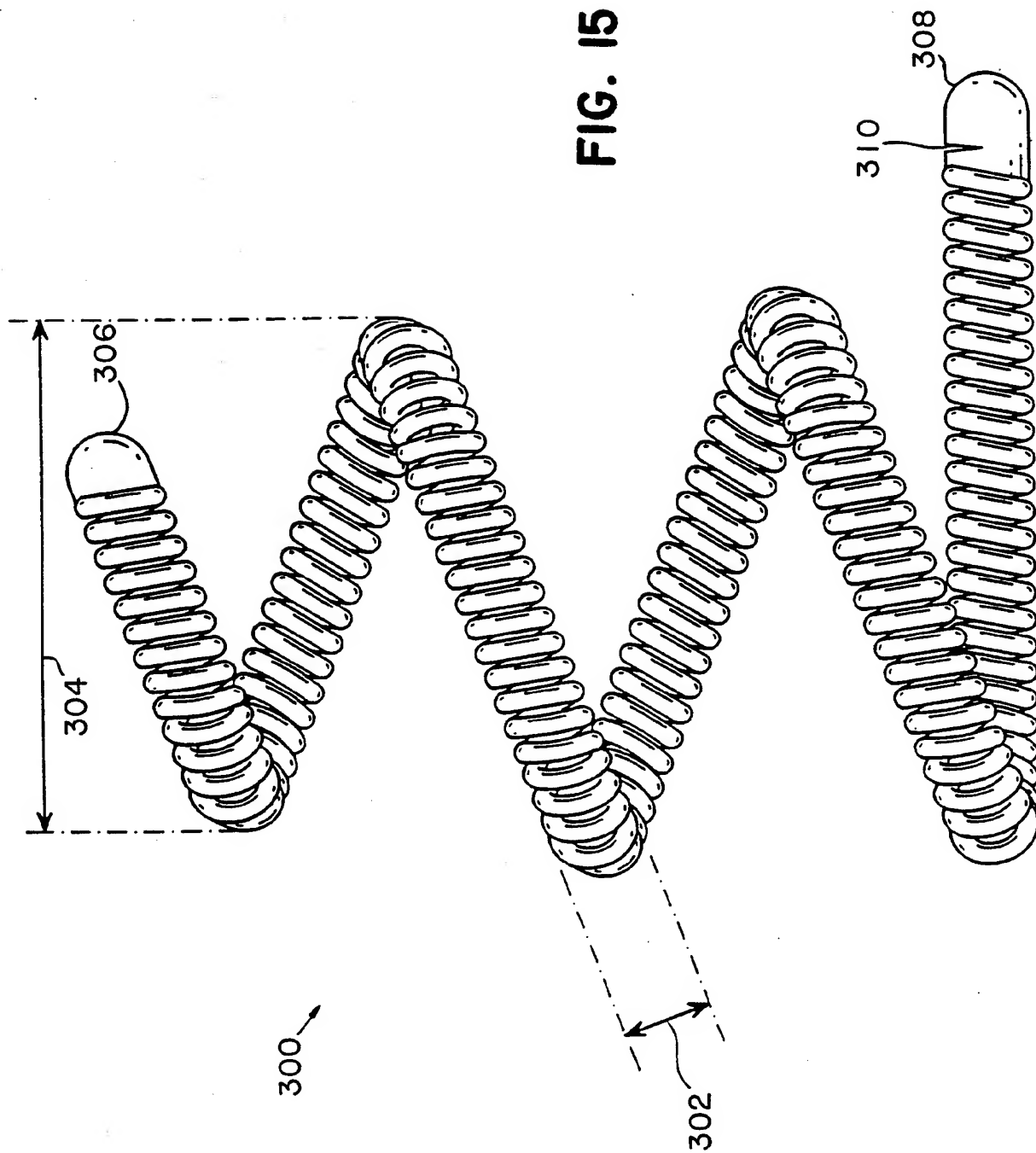
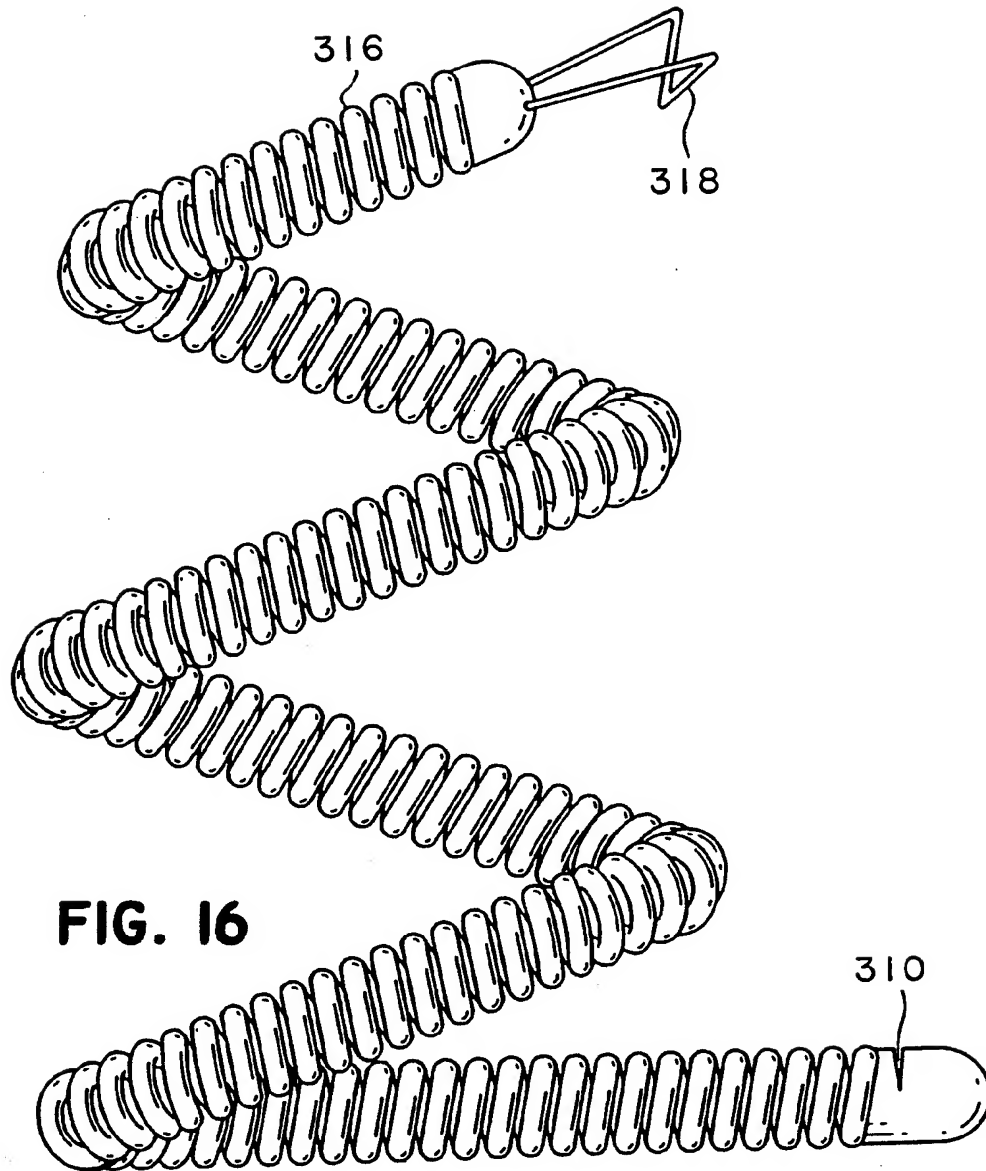


FIG. 14

FIG. 15



7 / 8



8 / 8

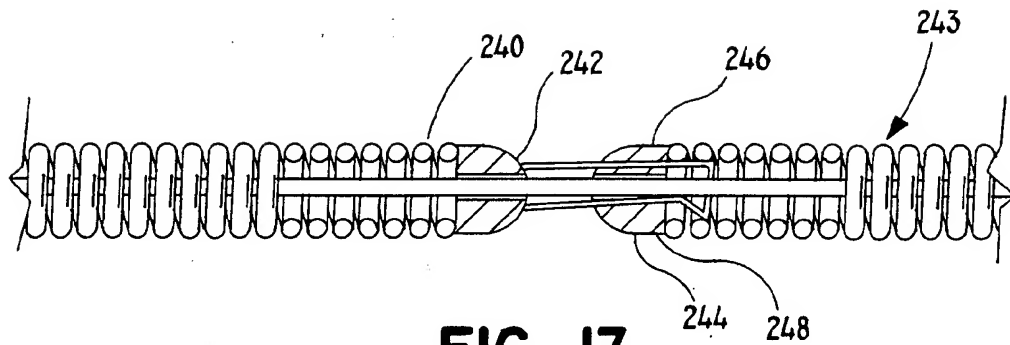


FIG. 17

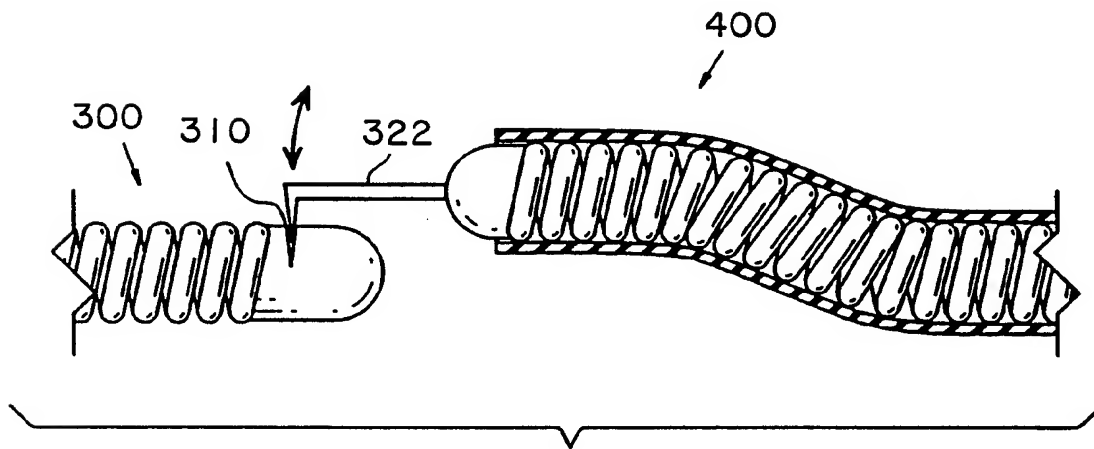


FIG. 18

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US93/08581

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61M 29/00

US CL : 606/198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1,12 128/898

606/152,153,108,194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

n/a

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

n/a

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 4,813,934 (Engelson et al.) 21 March 1989.	
A	US,A, 5,122,136 (Guglielmi et al.) 16 June 1992.	
A	US,A, 5,108,407 (Geremia et al.) 28 April 1992, See figure 4.	
A	US,A, 4,884,579 (Engelson) 05 December 1988.	
A	US,A, 4,739,768 (Engelson) 26 April 1988.	
A	US,A, 4,994,069 (Ritchart et al.) 19 February 1991.	
A	US,A, 5,109,867 (Twyford, Jr.) 05 May 1992.	

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A document defining the general state of the art which is not considered to be part of particular relevance	*X	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E earlier document published on or after the international filing date	*Y	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z	document member of the same patent family
*O document referring to an oral disclosure, use, exhibition or other means		
*P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

24 November 1993

Date of mailing of the international search report

FEB 02 1994

 Name and mailing address of the ISA/US
 Commissioner of Patents and Trademarks
 Box PCT
 Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer

J.L. Kruter

Telephone No. (703) 308-2114